IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. Action No._____
ALPHAPHARM PTY LTD.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, "Janssen"), and Synaptech, Inc. (collectively, "Plaintiffs"), by their attorneys, for their complaint against Alphapharm Pty Ltd. ("Alphapharm"), allege as follows:

The Parties

1. Plaintiff Janssen Pharmaceutica N.V., a wholly owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

2. Plaintiff Janssen, L.P., a wholly owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

3. Plaintiff Synaptech, Inc. ("Synaptech") is a company organized and existing under the laws of the State of New York and has its principal place of

business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

4. Upon information and belief, Defendant Alphapharm is a corporation organized and existing under the laws of Australia and has its principal place of business at Chase Building 2, 1 Wentworth Park Road, GLEBE NSW 2037, AUSTRALIA. Alphapharm does business in the State of Delaware, and Delaware pharmacists dispense, and Delaware residents consume, large numbers of prescription drugs manufactured and sold by Alphapharm, including many manufactured and sold pursuant to an approved Abbreviated New Drug Application ("ANDA").

Jurisdiction and Venue

5. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 4,663,318 ("the '318 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Alphapharm has consented to the jurisdiction of the United States District Court for the District of Delaware in connection with this lawsuit. In addition, Alphapharm is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its having conducted business in the State, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for Approval of New and Generic Drugs

8. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

9. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an abbreviated new drug application for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the pioneering drug, or, if the rate of absorption differs, that such difference is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(8)(B).

10. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-

back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

11. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

12. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

Plaintiffs' Approved Drug Product

13. Janssen is the holder of an approved new drug application, NDA No. 21-169, for galantamine hydrobromide tablets. That NDA was approved by FDA on February 28, 2001 and covers three strengths of tablet – Eq. 4 mg base, 8 mg base, and 12 mg base. The sole indication or condition of use for which galantamine hydrobromide tablets are approved in NDA No. 21-169 is the treatment of mild to moderate dementia of the Alzheimer's type.

14. Pursuant to FDA's approval, Janssen currently markets galantamine hydrobromide tablets for the treatment of mild to moderate dementia of the Alzheimer's type under the trademark RAZADYNE®. Until this year, Janssen marketed its galantamine hydrobromide tablets under the trademark REMINYL®.

15. FDA has listed the '318 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-169.

16. The '318 patent qualifies for listing in the Orange Book in connection with NDA No. 21-169 because it claims an approved use of the drug product that is the subject of that NDA. Alphapharm has never challenged the listing of the '318 patent in the Orange Book.

Alphapharm's ANDA

17. Alphapharm has represented that on or before May 11, 2005, it submitted to FDA an ANDA (ANDA No. 77-603) and Paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for galantamine hydrobromide tablets purportedly bioequivalent to Plaintiffs' RAZADYNE® products. The purpose of Alphapharm's ANDA and Paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide tablets before the expiration of the patents listed in the Orange Book for Janssen's NDA No. 21-169. Hence, Alphapharm's purpose in submitting ANDA No. 77-603 is to market in the United States the galantamine hydrobromide products described therein before expiration of the '318 patent.

18. Upon information and belief, the sole condition of use for which Alphapharm seeks approval in its ANDA No. 77-603 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in Janssen's NDA No. 21-169.

19. Upon information and belief, the sole indication set forth in the proposed labeling submitted by Alphapharm in its ANDA No. 77-603 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for Plaintiffs' REMINYL® and RAZADYNE® tablets.

Count 1: Patent Infringement

20. Plaintiffs reallege Paragraphs 1 through 19 above as if fully set forth herein.

21. On May 5, 1987, the United States Patent and Trademark Office duly and legally issued the '318 patent, entitled "Method of Treating Alzheimer's Disease." The term of the '318 patent runs through December 14, 2008. A true and correct copy of the '318 patent is attached hereto as Exhibit A.

22. Synaptech is the owner of the '318 patent.

23. Janssen is the exclusive licensee under the '318 patent, pursuant to an exclusive license agreement between Synaptech and Janssen, of the right to develop, make, have made, keep, use, market, sell, and/or dispose of certain pharmaceutical preparations containing galantamine hydrobromide to treat Alzheimer's disease in the United States and other territories. Pursuant to that exclusive license, Janssen currently markets galantamine hydrobromide tablets in the United States under the trademark RAZADYNE® and previously marketed galantamine hydrobromide tablets in the United States under the trademark REMINYL®. The conditions of use for which RAZADYNE® and REMINYL® are approved fall within one or more of the claims of the '318 patent.

24. As exclusive licensee, Janssen is authorized to enforce the '318 patent.

25. The conditions of use for which Alphapharm seeks approval in its ANDA No. 77-603 fall within one or more of the claims of the '318 patent. If approved, use of Alphapharm's proposed galantamine hydrobromide products in accordance with the proposed labeling for those products submitted in ANDA No. 77-603 would constitute a use of the product claimed in one or more of the claims of the '318 patent.

26. Alphapharm is liable for infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 77-603 with a Paragraph IV certification seeking FDA approval of ANDA No. 77-603 prior to expiration of the '318 patent.

27. Upon information and belief, if approved, Alphapharm's galantamine hydrobromide products for which approval is sought in Alphapharm's ANDA No. 77-603 will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer's type, which administration would constitute direct infringement of the '318 patent. Upon information and belief, this infringement will occur at Alphapharm's behest, with its intent, knowledge, and encouragement, and Alphapharm will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '318 patent.

28. Alphapharm's offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '318 patent, of the galantamine hydrobromide products for which approval is sought in ANDA No. 77-603,

would actively induce and contribute to infringement of the '318 patent, and Alphapharm would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c). Alphapharm's use in the United States of the galantamine hydrobromide products in accordance with the labeling for which approval is sought in ANDA No. 77-603 prior to expiration of the '318 patent would infringe the '318 patent, and Alphapharm would be liable as an infringer under 35 U.S.C. § 271(a).

29. Alphapharm had actual and constructive notice of the '318 patent prior to filing its ANDA No. 77-603, and Alphapharm's infringement of the '318 patent has been, and continues to be, willful.

30. Plaintiffs will be irreparably harmed if Alphapharm is not enjoined from infringing or actively inducing or contributing to infringement of the '318 patent. Plaintiffs do not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Alphapharm has infringed the '318 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment providing that the effective date of any FDA approval of the Alphapharm ANDA No. 77-603 for galantamine hydrobromide Eq. 4 mg base, 8 mg base, and 12 mg base tablets be not earlier than the expiration date of the '318 patent;

C. A judgment declaring that Alphapharm's manufacture, use, sale, offer for sale, or importation into the United States of the galantamine hydrobromide products for which approval is sought in ANDA No. 77-

603 would constitute infringement of the '318 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

D. A permanent injunction enjoining Alphapharm and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the galantamine hydrobromide tablets for which approval is sought in ANDA No. 77-603, or any galantamine hydrobromide product that infringes or induces or contributes to the infringement of the '318 patent, until expiration of that patent;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

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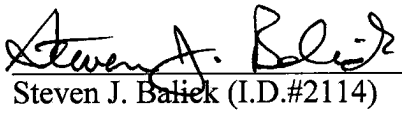

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